Smallpox

On December 13, 2002, the President announced a plan to better protect the Nation against the threat of smallpox attack by hostile groups or governments. The Department of Health and Human Services and CDC were directed to work with state and local governments to form volunteer Smallpox Response Teams. These teams would provide critical public health and healthcare services in the event of a smallpox attack. The President also instructed the Department of Defense to administer smallpox vaccine to certain members of the military.

To ensure that Smallpox Response Teams could mobilize immediately in an emergency, healthcare and public health workers were asked to volunteer to receive smallpox vaccine. The goal was to vaccinate a cohort of public health and healthcare workers. Vaccination of the general public was not recommended. The civilian vaccination program officially began on January 24, 2003.

As of August 8, 2003, a total of 38,257 civilians have been vaccinated. Vaccination of civilian volunteers has occurred in all 50 states and the District of Columbia. About 12 thousand vaccinated persons are public health response team members. The vast majority of the remaining vaccinated persons are healthcare response team members. More than 2 thousand hospitals have at least one vaccinated healthcare team member.

Safety in administering smallpox vaccine has been a high priority for both the civilian and military smallpox vaccination programs. Smallpox vaccine adverse reactions have been carefully monitored since the smallpox vaccination program began in January 2003. Surveillance for adverse events is being conducted by CDC, the Food and Drug Administration, and state health departments.

As of July 25, 2003, among civilians, 24 cases of inadvertent inoculation have been reported, 3 of which involved the eye. Three cases of generalized vaccinia and one possible case of post vaccination central nervous system involvement have been reported. No cases of eczema vaccinatum, progressive vaccinia, or fetal vaccinia have been reported.

Soon after the vaccination programs began in both civilian and military populations, a variety of cardiac events began to be detected among vaccinated persons. Symptoms ranged from those of myocarditis and pericarditis to ischemic symptoms, such as angina pectoris, and myocardial infarction. Myocarditis and pericarditis had been reported following smallpox vaccination in the 1950s and 1960s, but were usually associated with vaccinia strains not used in the U.S. vaccine. The incidence of these conditions among vaccine recipients was not known with certainty.

As of July 25, 2003 a total of 22 cases of myopericarditis have been reported among civilian vaccinees. The onset of symptoms was usually 1 to 2 weeks after vaccination, with a median of 11 days. The age of persons with myocarditis and/or pericarditis ranged from 25 to 70 years. Most cases have been mild to moderate. Ten persons required hospitalization for an average of 2 days. More than 90 percent of the persons with myopericarditis had been vaccinated in the past.

Myocarditis and pericarditis have also been reported among the 480 thousand vaccinated military personnel. A summary of the first 18 cases among military vaccinees was reported in the June 25, 2003 issue of the Journal of the American Medical Association.

The onset of myopericarditis in relation to smallpox vaccination, and the frequency of the reports among vaccinated persons, suggests that the association may be real. The association of other cardiac events, such as myocardial infarction is biologically plausible, but data are insufficient to determine if there is a causal relationship.

CDC issued a health alert and a press release concerning the possible cardiac complications of smallpox vaccination on March 25, 2003. As a precautionary measure, CDC recommended that persons diagnosed as having a heart condition, with or without symptoms, should NOT be vaccinated at this time.

These conditions include known coronary artery disease, angina or myocardial infarction, congestive heart failure, cardiomyopathy, chest pain or shortness of breath with activity, stroke or transient ischemic attack, and other heart conditions being treated by a doctor, such as valvular heart disease. In addition, persons should NOT receive smallpox vaccine if they have 3 or more risk factors for heart disease, including hypertension, hypercholesterolemia, diabetes, a first degree relative with a heart condition before the age of 50, or current smoking.

Persons with suspected cardiac events following smallpox vaccination will continue to be investigated. In addition, we strongly encourage clinicians caring for vaccinated persons to promptly report suspected adverse events to their state health departments. Updated information on this and other aspects of the smallpox vaccination program will be posted on the CDC smallpox website.

The Advisory Committee on Immunization Practices reviewed adverse reaction data and discussed the smallpox vaccination program at length at it’s June 2003 meeting. ACIP reiterated that it is critical for smallpox preparedness planning, within the context of broader terrorism and emergency response planning, to continue at the federal, state and local levels.

However, the ACIP felt that it is unwise to expand beyond its current, pre-event smallpox vaccination recommendations because of the new and unanticipated

safety concerns, such as myopericarditis, whose extent and severity, particularly of long term sequelae, are not yet known. ACIP recommended that any smallpox vaccination that occurs should be carried out only within the context of the currently recommended response teams and state and local response plans, and should be administered according to currently recommended vaccination procedures and protocols.

We asked Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention, for her perspective on the progress of smallpox preparedness, including the smallpox vaccination program.

> **Dr. Gerberding:** Thank you for your support of CDC's smallpox preparedness program. Since December, when President Bush announced the national smallpox vaccination policy, we have made important steps toward our goal of ensuring we can protect the public if a smallpox attack should occur. Immunization of key responders is one important component of smallpox preparedness, but there are other important elements that must also be addressed.
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> This graphic includes most of the key components of a comprehensive smallpox preparedness program. Red indicates a less prepared state, yellow indicates significant progress, and green indicates a highly prepared state. If we look at this in terms of where we started and where we are now, amazing progress has been achieved.
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> First, we have successfully contracted for the new smallpox vaccine, and delivery is on time. We have enough doses of vaccine to protect our nation, and we have about 290,000 doses in the field. We have provided information to 3.5 million clinicians, and have established a hotline to answer medical questions. 70 percent of the Laboratory Response Network labs around the country can rapidly diagnose vaccinia and other conditions that could be confused with smallpox, and an increasing number can definitely rule in smallpox.
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> As you have just heard, we have a highly effective system for screening people at risk for vaccine complications, and our overall serious complication rate is actually lower than we had predicted. With your help, we have also implemented a comprehensive vaccine safety monitoring system, which helped us detect unexpected events such as myopericarditis that emerged in the last few months.
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> We still have challenges in detection and reporting, hospital preparation, and vaccine clinic planning. Even though we have immunized more than 38,000 people, we don't have adequate pre-event vaccination to ensure we can safely care for the first smallpox patient in all jurisdictions, though again significant progress has been made in the past 6 months. We must sustain our efforts to prepare for smallpox. The threat is not zero and we have no indication that it is any less now than it was before we started this endeavor. Even though an attack is not imminent, as we learned with SARS, the consequences of a smallpox attack will be devastating unless we are prepared to fully protect our population.
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> Thank for all you are doing to support this effort.